510(k) Summary

MAR 2 1 2012

HEITER 3000 HYPERTHERMIC PERFUSION SYSTEM

K102900

General Information

Classification	Unclassified
Product Code:	LGZ
Classification Name:	Warmer, Thermal, Infusion Fluid
Trade Name	HEITER 3000 Hyperthermic Perfusion System
Submitter	HEI, Inc. 4801 N. 63rd Street Boulder, CO 80301 Tel: 720.622.4216
Contact	Chuck Russo General Manager

Indications for Use

The HEITER 3000 Hyperthermic Perfusion System is intended to raise the temperature of the thoracic or peritoneal cavity to a physician selected target temperature by continuously lavaging the cavity with a sterile circulating, warmed, physiologically compatible solution such as sterile saline or Lactated Ringers.

Predicate Devices

K092366	TTS100 Portable Hyperthermic Perfusion Device Thermal Therapeutic Systems, Inc
K070654	Belmont Hyperthermia Pump Belmont Instruments

Device Description

The HEITER 3000 is comprised of two components: a portable control console and a single use disposable. The Console consists of a heater, pump, user touch screen, microprocessor, and interface electronics.

The primary user interface is a color touch screen display that allows the user to make selections from the operating screen consisting of message display area, main screen area and flow control area.

The touch screen also displays operating conditions, flow rate, output fluid temperature, patient temperature, target temperature, alarm and status messages, various timers and auxiliary temperatures. The HEITER 3000 monitors various sensors in the fluid path to ensure safe operation and alerts the user with alarms for out of specification conditions. Independent protection circuits prevent unsafe operation in the event of system software fault.

The disposable single-use Lavage Procedure Kit consists of a Tubing Set, Cannulae, Temperature Probes and a Fluid Reservoir. The Lavage Procedure Kit is supplied sterile.

Technological Characteristics Comparison to Predicate Devices

As compared to the predicate devices, the HEITER 3000 Hyperthermic Perfusion Device has the same operating principle, energy type, environmental specifications, and performance specifications. All of the devices use a roller-type fluid pump, touchscreen-based clinical user interface for machine set-up and control, sensor monitoring of various fluid temperatures, and a proprietary-design disposable set including large fluid reservoir to circulate sterile fluid into and out of the body cavity. In the HEITER 3000, fluid in the reservoir is directly heated to the desired temperature, the heater drain tubing passes through a roller pump and out to the patient inlet. Fluid returns from the patient outlet via gravity drain back to the fluid reservoir. The HEITER 3000 monitors circulating fluid temperature and pressure, and automatically responds to ineffective or unsafe operating conditions.

Software Verification / Validation Testing

As part of the software verification/validation activities, and in support of substantial equivalence, the following tests were carried out on the HEITER 3000 to evaluate its ability to meet product performance specifications. Specifically, the HEITER 3000 was tested to assess its ability to:

- heat fluids over the full range of fluid flow rates.
- maintain fluid temperature over the full range of fluid flow rates.
- detect and automatically respond to unsafe or ineffective operating conditions, as caused by the failure of the system sensors, excessive fluid temperature, excessive fluid pressure, or system-internal component failures.
- inform the clinical user of those unsafe or ineffective operator conditions via notifications, alerts, alarms, and/or system faults.
- mitigate against unknown or predictable operator errors.
- store non-patient, procedure specific treatment parameters and machine data in non-volatile memory.
- measure temperature accuracy over the full range of fluid flow rates within the operating pressure range.
- measure pressure accuracy over the full range of fluid flow rates within the operating temperature range.
- measure fluid flow rate accuracy over the full range of fluid flow rates within the operating temperature pressure range.

The HEITER 3000 performed within specifications in all of the above tests.

Human Factors / Non-Clinical Study Testing

A human factors non-clinical study was performed, providing diverse groups of pump users with a product inservice on the HEITER 3000, and testing those groups on the setup and performance of a simulated hyperthermic lavage procedure on the HEITER 3000. The testing identified potential user and patient safety risks associated with the design of the HEITER 3000, and the results demonstrated that the task-risks have successfully been addressed and mitigated.

Verification of Safety Requirements

The HEITER 3000 is designed to, does comply with, and has been tested as part of verification and validation testing to the FDA Recognized Consensus Standards listed below, as is applicable to the features and components of the HEITER 3000.

Electrical Safety, EMC	**IEC 60601-1:1998+A1:1991+A2:1995 (IEC 60601-1+A1+A2)**	**Medical Electrical Equipment – Part 1: General Requirements for Safety, 1998; Amendment 1, 1991-11, Amendment 2, 1995**
	IEC 60601-1-2:2001+A1:2004 (IEC 60601-1+A1+A2)	**Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Test (Ed. 2.1)**

Biocompatibility	**AAMSI/ANSI/ISO 11135-1:2003(E)**	**Biological evaluation of medical devices - Part 1: Evaluation and Testing**
	AAMSI/ANSI/ISO 10993-1:2007	**Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity**
	AAMSI/AMSI/ISO 10993-7:1995(R)2001	**Biological evaluation of medical devices - Part 7: Ethylene Oxide Sterilization Residuals**
	AAMSI/ANSI/ISO 10993-10:2002	**Biological evaluation of medical devices - Part 10: Tests for Irritation and Delayed-type Hypersensitization**
	AAMSI/ANSI/ISO 10993-11:2006	**Biological evaluation of medical devices - Part 11: Tests for Systemic Toxicity**

Sterility	**AAMSI/ANSI/ISO 10993-1:2003(E)**	**Sterlization of Health Care Products – Ethylene oxide – Part 1: Requirement for the the development, validation, and routine control of a sterilization process for medical devices**

Packaging	**ASTM D4169-05:2005**	**Sterlization of Health Care Products – Ethylene oxide – Part 1: Requirement for the the development, validation, and routine control of a sterilization process for medical devices**

Summary of Substantial Equivalence

Based upon safety and performance testing and compliance with voluntary standards, HEI, Incorporated believes that the HEITER 3000 Hyperthermic Perfusion Device is substantially equivalent to the features of the predicate products, and does not raise any new questions of safety or effectiveness. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gregory Mathison
Regulatory Affairs
HEI, Inc.
4801 N. 63rd Street
Boulder, Colorado 80301

MAR 2 1 2012

Re: K102900
Trade/Device Name: HEITER 3000 Hyperthermic Perfusion System
Regulation Number: None
Regulation Name: None
Regulatory Class: II
Product Code: LGZ
Dated: January 27, 2012
Received: January 30, 2012

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name:	HEITER 3000 Hyperthermic Perfusion System
510(k) Number (if known):	K102900
Indications for Use:	The HEITER 3000 Hyperthermic Perfusion System is intended to raise the temperature of the thoracic or peritoneal cavity to a physician selected target temperature by continuously lavaging the cavity with a sterile circulating, warmed, physiologically compatible solution such as saline or Lactated Ringer's.

X
Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102900

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